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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,046	06/29/2007	David W. Old	17795 PCT US (AP)	3455
51957	7590	07/18/2008		
ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599				
EXAMINER				
SHITERENGARTS, SAMANTHA L				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
07/18/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/599,046

**Applicant(s)**

OLD ET AL.

**Examiner**

Samantha L. Shterengarts

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-16, and 18-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 4, 17, and 20 are cancelled. Claims 1-3, 5-16, and 18-19 are currently pending. Claims 1, 3, 6, 7, 12, 15, and 16 are currently amended. Receipt and consideration of Applicants' amended claim set and remarks/arguments filed 21 May 2008 is acknowledged and entered.

#### ***Response to Arguments***

2. Applicant's arguments, see pages 6-12 regarding 112 1<sup>st</sup> rejection and pages 14-17 regarding 112 2<sup>nd</sup> rejection, filed 21 May 2008, with respect to claims 1-20 have been fully considered and are persuasive. The 112 1<sup>st</sup> rejection of claims 1-20 with regards to the enablement of compounds with substituent A wherein carbon atoms have been replaced with S or O and the 112 2<sup>nd</sup> rejection of claims 1, 5, 8, 12, and 15-16 with regards to the phrases, "where 1 or 2 carbon atoms may be replaced by S or O" "interthienylene" "interheteroaryl" "interaryl" and "interthienyl" have been withdrawn.

3. Applicant's arguments filed 21 May 2008 regarding double patenting rejection (see pages 17-18) have been fully considered, but they are not persuasive. Applicants' amendment and cancellation of claims has necessitated the change of claim numbers in this rejection; however, the rejection itself is the same, with explanation added.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

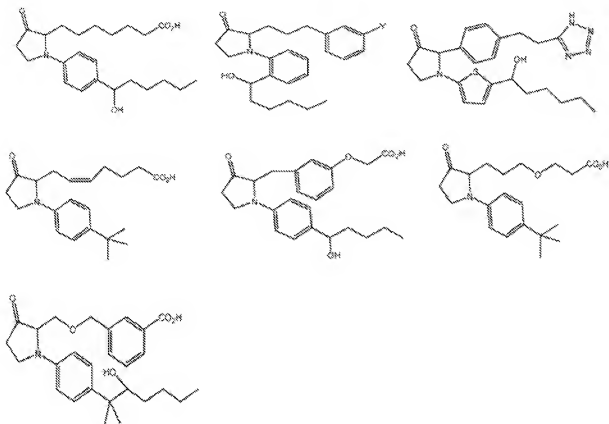
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-3, 5-16, and 18-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/778,800 and claims 1-20 of copending Application No. 11/747,490. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons below.

Determining the scope and contents of Claims 1-20 of Co-pending application No. 11/747,490 and 11/778,800

Claims 1-20 of co-pending application no. 11/778,800 and claims 1-20 of copending application no. 11/747,490 disclose numerous positional isomers of the instant claims (when J is C=O in the instant application).

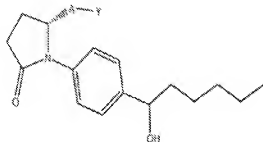
Positional Isomers from the Specifications of 11/778,800 and 11/747,490 (pages 21-26 of both):



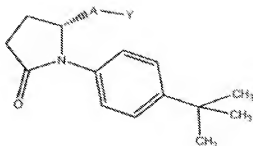
Examples of corresponding subgenera from the instant specification for which the positional isomer species identified *supra* obviate:

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Page 17:



Ascertaining the differences between Claims 1-20 of Co-pending application No. 11/747,490,

Claims 1-20 of Co-pending application No. 11/778,800 and instant claims 1-3, 5-16, and 18-19

Claims 1-20 of co-pending application No. 11/747,490 and claims 1-20 of co-pending application No. 11/778,800 disclose a generic compound with various substituents on the ring, methods of treating glaucoma or ocular hypertension, and a composition comprising a compound of the claim 1 with an ophthalmically acceptable liquid. This generic compound of both co-pending applications are drawn to positional isomers of instant claims 1-3 and 5-16, positional isomers being administered for the method of treating glaucoma or ocular hypertension of instant claim 18, and positional isomers of the composition of instant claim 19, as evidenced by the structures above.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness

Applicant's representative asserts that there is no compound that would infringe the present claims that would also infringe a claim in either of these other applications and therefore there is no way Applicant could use these later applications to extend the exclusivity of any embodiment protected by the claims or harass multiple parties by assigning these applications to different parties. This argument is not found persuasive because, while there is no compound

that anticipates the instant application in either of these co-pending applications, there are however, numerous compounds that obviate the instant claims through positional isomerism.

Positional isomers are generally of sufficiently close structural similarity because there is a presumed expectation that such compounds possess similar properties. MPEP §2144.09, *Ex parte* Henkel 130 USPQ 474, (1-phenyl-3-methyl-4-hydroxypyrazole) obvious over reference teaching (3-phenyl-5-methyl-4-hydroxypyrazole). *Ex parte* Weston, 121 USPQ 429.

One of ordinary skill would be motivated to make the positional modifications required to arrive at the instant invention with reasonable expectation for success of obtaining a compound that is active for the treatment of glaucoma or ocular hypertension. Examiner expects the positional isomers would retain the activity of the instantly claimed compounds, especially since the disclosure of both copending applications uses these prostaglandin compounds for the same utility. It is obvious to one of ordinary skill to make this modification with reasonable expectation for success. The motivation to make this modification would be to make alternate compounds for the quoted purpose.

### ***Conclusion***

5. Claims 1-3, 5-16, and 18-19 are rejected. No claims are allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/  
Examiner, Art Unit 1626

/Kamal A Saced, Ph.D./  
Primary Examiner, Art Unit 1626